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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,355	05/12/2008	Lawrence Solomon	ABT-054	2979

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ACCU-BREAK TECHNOLOGIES, INC.
1000 SOUTH PINE ISLAND ROAD
SUITE 230
PLANTATION, FL 33324

EXAMINER	
LOVE, TREVOR M	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
08/11/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,355	SOLOMON ET AL.	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-65,67-71 and 76-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-65,67-71 and 76-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 53-65, 67-71, and 76-80 are pending.

Claims 1-52, 66, and 72-75 are cancelled.

Claim 80 is newly added.

Claims 53-56, 59, 61, and 62 are currently amended.

Claims 53-65, 67-71, and 76-80 are currently under consideration.

NOTE: Claim 53 is improperly identified as "previously presented". Claim 80 underlines several terms, wherein said underlining is improper in view of the entire claim being "New".

Withdrawn Rejections and/or Objections

The objection to claims 54-56 for containing informalities has been withdrawn in view of Applicant's amendments to said claims.

The rejection of claims 56-66, 69-71, and 78-79 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicant's amendments to claims 56, 61, and 62, and Applicant's cancellation of claim 66.

Maintained Rejections, New Grounds of Rejection for newly added claim 80

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 53-71 and 76-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms - tablets, 1990) in view of Ullman et al (U.S. Patent number 4,215,104, Patent issued Jul. 29, 1980).

Lieberman teaches a pharmaceutical dosage form with layers. Lieberman teaches that it is known to have a tablet wherein the center layer is free of active. Lieberman teaches said middle inert layer for when the two outer actives are incompatible (see first paragraph under "IV. Layer Tablets"). Lieberman further teaches that it is known to place scores on tablets to allow for manual breakage, however, Lieberman acknowledges that traditional scores result in significant variation in drug dose (see point number 4 under "Properties of Tablets"). Said layered tablets are taught as 2 or 3 layers of granulation compressed together wherein said layers can have different coloring to allow for unique tablet identification.

Lieberman fails to directly teach how deep of a score the tablet should have, that the height of the tablet is greater than the width, that the two actives used with the drug-free intermediate layer are compatible, that the score is 70% of the horizontal dimension or width, that there is a vertical separation mark, or that the tablet is covered with an inert or pharmaceutically inactive composition. These deficiencies are made up for in the teachings of Ullman.

Ullman teaches a multi-fractionable unitary tablet structure. As can be seen by figure 3, the tablet can have a height which is greater than the width of the tablet, and the center section is thicker than the thickness of both the top and bottom sections together. It is noted that Ullman does not require the presence of a semi-permeable

membrane coating, a drug over-coating, or an osmotically active component. The tablet has a score which transverses the entire tablet (note 112 second paragraph rejection of claim 66 above). The tablet can also have scores on the vertical axis (see figures 1, 2, 4-6, 9-12, 14, and 15). The tablet can be colored to reflect particluar dosage units (see column 7, lines 39-43). Said tablet can comprise a coating by coating materials well known in the art (see column 7, lines 43-45), which could be considered a capsule.

It would have been obvious to one or ordinary skill in the art at the time the invention was made to utilize the tablet structure of Ullman with the layers described in Lieberman. One would have been motivated to do so since Ullman provides a clear teaching of a superior scored tablet which allows for the tablet to be broken into three separate dosages in addition to breaking the tablet in half. There would be a reasonable expectation of success since both Lieberman and Ullman are teaching scored tablets.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the top and bottom portion of the tablet design of Ullman for the incompatible active ingredients of Lieberman. One would have been motivated to do so since Lieberman teaches that variable dosing is a well known problem in the art associated with breaking dosage forms. Furthermore, utilizing the top and bottom segment of Ullman allows for breakage to only occur in the inert barrier layer. There would be a reasonable expectation of success since Lieberman teaches that trilayered tablets with an inert barrier layer can be scored.

It would further have been obvious to one of ordinary skill in the art at the time the invention was made, given the scored trilayered tablet of Lieberman and Ullman which comprises two incompatible drugs separated by a barrier layer, to replace said incompatible drugs with compatible drugs (which includes identical drugs). One would have been motivated to do so since the scored trilayered tablet of Lieberman and Ullman overcomes the well known problem in the art of variable dosages, wherein it is noted that Lieberman teaches that compatible drugs can also be located in a layered tablet. The multilayered tablets of Lieberman can have either incompatible or compatible layers, and therefore, one would have been motivated to utilize either compatible or incompatible layers since the problem in the art of variable dosages is not restricted to only incompatible multilayered tablets. There would be a reasonable expectation of success since whether the drugs are compatible or not does not affect the dosage of Lieberman and Ullman.

With regard to the effective height of the inner segment, it is the position of the Examiner that absent evidence to the contrary, the size of a tablet can be readily optimized to allow for a tablet which is appropriately sized for the patient for whom the tablet is intended. Altering the size of the tablet would not inherently have an effect on the function of the tablet, particularly when said altering is being done to a layer which is drug-free.

Response to Arguments and Declaration

Applicant argues in the response and declaration filed 06/11/2010 that the Declaration of Elliot Hahn shows that the results achieved by the tests conducted and

recorded in the declaration could not be predicted from any disclosure in Lieberman or Ullman. Applicant's argument is not found persuasive since the instant tests recorded are not commensurate in scope with the instant invention. For instance, claim 53 states the composition comprises "a score greater than 50% through the maximum height of one of said first or second segments". Note that there is no indication in claim 53 as to the height of the non-scored segment. Therefore, for example, should Applicant break through an unscored second layer which comprises 95% of the tablet weight, it is unclear how Applicant would achieve the results discussed in the declaration. Therefore, since it appears that the invention tested in the declaration differs greatly in scope from that of the instant invention, the declaration is not found persuasive. Applicant further argues that Lieberman fails to describe a tablet having an inactive outer segment as expressly recited in claim 53. Applicant's argument is not found persuasive since, as set forth above, there is clear motivation to arrive at a two layered tablet. As such, each of said two layers would necessarily be "outer segments". Applicant further argues that neither Lieberman nor Ullman teaches a "taller-than-wide" tablet. Applicant's argument is not found persuasive since first, it is noted that Applicant is claiming a product, rather than a method. Second, Lieberman teaches three layered tablets, wherein one would have been motivated to utilize the tablet design and scores of Ullman for said tablet. Applicant appears to believe that one would place the composition in a very particular die in a particular orientation, however, Applicant is again reminded that Applicant is claiming a product and not a method, therefore, the structural limitations are the salient issues. One making the above identified tablets as

taught and motivated by Lieberman, given the advantageous structure of Ullman would have utilized known methods for said compressed composition. Since there are only two main types of orientation it clearly would have been obvious to utilize either (see for instance U.S. Patent number 4,139,589). Both tablet orientations are well known in the art. One would have desired the vertical orientation since that would be the only orientation that would achieve breakage through the inert layer. Therefore, Applicant's argument is not found persuasive. Finally, Applicant argues that "[t]here is nothing in the prior art that teaches or suggests modification of one segment and not the other two segments in a three-segment tablet". Applicant's argument is not found persuasive since, if nothing else, dosing is a known teaching that exists in the prior art for why one would modify one segment and not the other two in a three-segment tablet.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 53-71 and 76-80 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 8 of copending Application No. 10/598,344 in view of Lieberman (Pharmaceutical Dosage Forms - tablets, 1990) and Ullman et al (U.S. Patent number 4,215,104, Patent issued Jul. 29, 1980). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The copending application teaches in copending claim 1 an immediate release pharmaceutical tablet having a first segment which contains a drug, a score, and a second segment, wherein said second segment does not contain a drug, this reads on **instant claim 53**.

'344 fails to recite a third layer. Lieberman and Ullman render it obvious to add an additional layer which reads on **instant claims 54-56**.

Lieberman teaches a pharmaceutical dosage form with layers. Lieberman teaches that it is known to have a tablet wherein the center layer is free of active. Lieberman teaches said middle inert layer for when the two outer actives are incompatible (see first paragraph under "IV. Layer Tablets"). Lieberman further teaches that it is known to place scores on tablets to allow for manual breakage, however, Lieberman acknowledges that traditional scores result in significant variation in drug dose (see point number 4 under "Properties of Tablets"). Said layered tablets are

taught as 2 or 3 layers of granulation compressed together wherein said layers can have different coloring to allow for unique tablet identification.

Ullman teaches a multi-fractionable unitary tablet structure. As can be seen by figure 3, the tablet can have a height which is greater than the width of the tablet, and the center section is thicker than the thickness of both the top and bottom sections together. It is noted that Ullman does not require the presence of a semi-permeable membrane coating, a drug over-coating, or an osmotically active component. The tablet has a score which transverses the entire tablet (note 112 second paragraph rejection of claim 66 above). The tablet can also have scores on the vertical axis (see figures 1, 2, 4-6, 9-12, 14, and 15). The tablet can be colored to reflect particluar dosage units (see column 7, lines 39-43). Said tablet can comprise a coating by coating materials well known in the art (see column 7, lines 43-45), which could be considered a capsule.

It would have been obvious to one or ordinary skill in the art at the time the invention was made to utilize the tablet structure of Ullman with the layers described in Lieberman with the invention of '344. One would have been motivated to do so since Ullman provides a clear teaching of a superior scored tablet which allows for the tablet to be broken into three separate dosages. There would be a reasonable expectation of success since '344, Lieberman, and Ullman are teaching scored tablets.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the top and bottom portion of the tablet design of Ullman for the incompatible active ingredients of Lieberman when modifying the invention of '344. One would have been motivated to do so since Lieberman teaches that variable

dosing is a well known problem in the art associated with breaking dosage forms. Furthermore, utilizing the top and bottom segment of Ullman allows for breakage to only occur in the inert barrier layer. There would be a reasonable expectation of success since Lieberman teaches that trilayered tablets with an inert barrier layer can be scored.

It would further have been obvious to one of ordinary skill in the art at the time the invention was made, given the scored trilayered tablet of Lieberman and Ullman which comprises two incompatible drugs separated by a barrier layer, to replace said incompatible drugs with compatible drugs. One would have been motivated to do so since the scored trilayered tablet of Lieberman and Ullman overcomes the well known problem in the art of variable dosages, wherein it is noted that Lieberman teaches that compatible drugs can also be located in a layered tablet. The multilayered tablets of Lieberman can have either incompatible or compatible layers, and therefore, one would have been motivated to utilize either compatible or incompatible layers since the problem in the art of variable dosages is not restricted to only incompatible multilayered tablets. There would be a reasonable expectation of success since whether the drugs are compatible or not does not affect the dosage of '344 as modified by Lieberman and Ullman.

With regard to the effective height of the inner segment, it is the position of the Examiner that absent evidence to the contrary, the size of a tablet can be readily optimized to allow for a tablet which is appropriately sized for the patient for whom the tablet is intended. Altering the size of the tablet would not inherently have an effect on

the function of the tablet, particularly when said altering is being done to a layer which is drug-free.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant argues in the remarks filed 06/11/2010 that in view of neither the instant or the copending claims being allowed, the obviousness-type double patenting rejection will be considered upon indication of allowable subject matter. Applicant's arguments are not found persuasive, and as such, the rejection is maintained and made again.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643